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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,121	11/30/2001	Richard R. Lunak	DB000970-000	4436

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EXAMINER

SHAPIRO, JEFFERY A

ART UNIT	PAPER NUMBER
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3653

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/998,121	Applicant(s) LUNAK ET AL.	
	Examiner Jeffrey A. Shapiro	Art Unit 3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14, 16-19, 21, 23-30, 32, 34-36, 38-44, 46, 48, 52 and 54-60 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-8, 10-12, 14, 16-19, 21, 23-30, 32, 34-36, 38-44, 46, 48, 52 and 54-60 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 10-12, 14, 16-19, 21, 23-30, 32, 34-36, 38-44, 46, 48, 52 and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 6,564,121 B1) in view of Awane et al (US 4,608,487). Wallace et al discloses the following.

As described in Claims 15, 26, 52 and 54-60;

- a. dispensing and administering medications and issuing medical/surgical supplies using a device communicating with a central database (see abstract);
- b. inputting information about a patient to the device for whom at least one medication may be dispensed and administered (see figure 16B, step 4);
- c. dispensing the at least one medication to the patient by inputting information about the at least one medication to the device (see figure 16C, step (7));

- d. saving the at least one medication to the patient selected (see figure 17C, button (1476);
- e. inputting information about a patient to the device for whom at least one medical/surgical supply may be issued (see col. 1, lines 43-47, col. 10, lines 40-43 and col. 11, lines 54-65);
- f. issuing the at least one medical/surgical supply to the patient by inputting information about at least one medical/surgical supply to the device (see figure 16C, step 7);
- g. saving the at least one medical surgical supply to the patient selected (see col. 32, lines 20-38 and col. 33, lines 4-18);
- h. recording the identity of the supply location (see figure 17C, noting that a "storage location", "PSY1" is identified in one of the fields of the "medication summary.");
- i. a touch screen (420) (see figure 7 and col. 14, lines 1-5);
- j. a radio communications unit (see col. 7, lines 41-47);

As described in Claims 2, 16, 27 and 38;

- k. the saving step (4) results in the automatic deduction of the at least one medication from an inventory list saved on the central database (see col. 11, lines 64-67 and col. 12, lines 1-12);

As described in Claims 3, 17, 28 and 39;

- l. the automatic deduction triggers an automatic reordering of the at least one medication from the central database if the automatic deduction

results in the inventory listing for that medication being less than a predetermined level assigned on the database for that medication (see col. 17, lines 54-65, noting that reorders are placed based upon inventory threshold stockout levels);

As described in Claims 4, 18, 29 and 40;

m. the saving step results in the automatic charging of the cost of the at least one medication to an invoice saved on the central database for the patient selected (see col. 11, lines 64-67 and col. 12, lines 1-12);

As described in Claims 5 and 41;

n. the saving step (7) results in the automatic deduction of at least one medical/surgical supply from an inventory list saved on the central database (see figures 18A-D);

As described in Claims 6 and 42;

o. the automatic deduction of claim 5 wherein the automatic deduction triggers an automatic reordering of the at least one medical/surgical supply from the central database if the automatic deduction results in the inventory listing for that medical/surgical supply being less than a predetermined level assigned on the database for that medical/surgical supply (again, note that inventory threshold stockout levels are used, which automatically trigger reorder when a particular lower level of inventory is reached);

As described in Claims 7 and 43;

p. regarding claim 6, wherein the saving step results in the automatic charging of the cost of the at least one medical/surgical supply to an invoice saved on the central database for the patient selected (see col. 11, lines 64-67 and col. 12, lines 1-12);

As described in Claims 8, 19, 30 and 44;

q. additionally comprising the step of logging the user onto the central database by inputting information into the device (see col. 18, lines 10-12);

As described in Claims 10, 21, 32, and 44;

r. the step of logging the user onto the central database is accomplished by typing a user ID and password on a menu of the device (see col. 18, lines 10-12);

As described in Claims 11 and 24;

s. the step of dispensing the at least one medication to the patient is done by scanning bar codes associated with the at least one medication (see col. 20, lines 20-29);

As described in Claim 12;

t. the step of dispensing the at least one medication to the patient is done by selecting the at least one medication from a menu on the device (see figure 29);

As described in Claim 14;

- u. the step of issuing the at least one medical/surgical supply to the patient is done by selecting the at least one medical/surgical supply from a menu on the device (see figure 16C, step 7);

As described in Claims 23, 25, 34-36 and 48;

- v. the step of selecting a patient for whom at least one medical/surgical supply will be issued is done by selecting a patient from a menu of the device (note that it would have been obvious to select a patient from a menu);

- 21a. the step of issuing the at least one medical/surgical supply is done by selecting the at least one medical/surgical supply from a menu on the device (see figure 29);

Wallace further discloses;

As described in Claims 13, 22, 33 and 47;

- x. the step of issuing the at least one medical/surgical supply to the patient is done by scanning bar codes associated with the at least one medical/surgical supply (see col. 20, lines 20-29);

As described in Claims 9, 20, 31 and 45;

- w. the step of logging the user onto the central database is accomplished by entering a identification (ID) assigned to the user (see col. 11, lines 54-61 and col. 12, lines 9-14);

Wallace does not expressly disclose, but Awane discloses the following.

As described in Claims 13, 22, 33 and 47;

z. the bar code also provides the location of the supply;

(See Awane figure 19B, element (119), and col. 18, lines 10-27, which shows the use of barcodes to represent location of items according to column. Note also that Awane generally teaches the representation of pertinent information in the form of a barcode.)

Wallace does not expressly disclose the following;

As described in Claims 9, 20, 31 and 45;

w. the step of logging the user onto the central database is accomplished by scanning a user barcode assigned to the user;

As described in Claims 54-60;

aa. using a personal digital assistant (PDA) with the system of Wallace to allow a medical caregiver to go to a patient's room, create administration records, then go to a supply room to scan a bar code associated with the supply identity as well as its location, and updating said records;

Both Wallace and Awane are analogous art because Wallace uses bar codes for representation of information while Awane teaches further representation of information by bar code, such as location of items.



At the time of the invention, it would have been obvious to one ordinarily skilled in the art to have used a barcode to identify a user to the system as it is a functional equivalent of inputting a login ID and that it would have been obvious to one skilled in the art to provide for this alternative format. See also Wallace, figures 11B-11C which show user id's being entered at (722, 732, 738, 760 and 762.)

It would also have been obvious to issue supplies by scanning bar codes as well as to provide the location of said supplies, or any other pertinent information in the form of a bar code as this is a recognized method of representing information to an automated/computerized system. See again, Awane, cited previously. See also, for example, Wallace, figure 13C, element (924), which indicates use of "dispensing coordinates" which are considered to be location data.

One ordinarily skilled in the art would recognize that based upon Awane's teaching, bar codes could be used to automate the input of information of any type, such as information used by Wallace for logging into the computer system or to represent supply information, such as location.

The suggestion/motivation would have been to "provide an input unit which is capable of easily coping with the changes in and the addition to input contents." See Awane, col. 2, lines 18-28.

Regarding Claims 54-60, note that it would have been obvious to one of ordinary skill in the art to have used the wireless, PDA-based system of Wallace to perform the methods described in these claims. One ordinarily skilled in the art would have recognized that a caregiver could use Wallace's PDA to go to a patient's room, create

records, as described at Wallace, col. 11, lines 64-67 and col. 12, lines 1-9, then scan a bar code associated with the supply as well as its location (see teaching of Awane) and then update said records with the new transaction.

Therefore, it would have been obvious use Wallace and Awane in order to obtain the invention as described in Claims 1-8, 10-12, 14, 16-19, 21, 23-30, 32, 34-36, 38-44, 46, 48, 52 and 54-60.

### ***Response to Arguments***

3. Applicant asserts that “administration of medications to a patient is distinct from the dispensing of medications for a patient.” However, Applicant’s claimed system does not preclude its use by either a patient or by a caregiver. In either situation, the system works the same to dispense items. For example, in the case where the caregiver is also the patient, the claim language is met. Also, regardless of who is administering or receiving the medical supplies, the system works the same. Wallace’s system, as described above, works in the same way as described by Applicant’s claim language. In fact, Applicant also mentions that “the exact sequence of events recited in all the method claims is not critical.” Applicant appears to intend to claim a “wireless, handheld point-of-care device that may be used to verify and chart medical administrations while providing a real time medication administration record.” This is what the system of Wallace does. Note also that nowhere in Applicant’s claims is the limitation for a wireless, handheld system present. Nonetheless, Wallace discloses that his system may be implemented as either a portable handheld personal digital assistant (PDA), a portable terminal or a notebook computer at col. 9, lines 37-48. Further, it would have

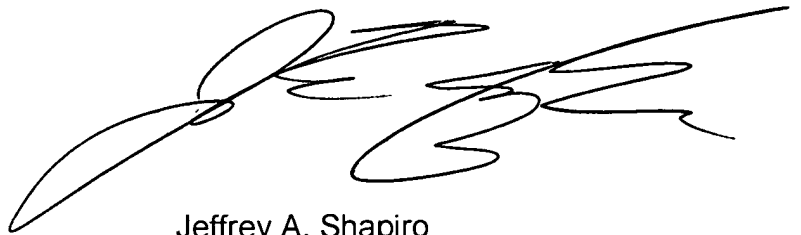
been obvious to use a wireless connection in place of a hardwired connection. Also, the system of Wallace, as described above, administers medical supplies in both local and remote locations and keeps records of all transactions. Even if the components of the system are remote from each other so that the PDA only does certain tasks, but the home computer, located remotely, performs the other tasks, this system would still be considered equivalent to Applicant's system, since the actual location of the parts of the system make no difference in its operation. Even if the entire system was hardwired with a large mainframe computer performing all tasks, this system would be equivalent to Applicant's claimed system.

Therefore, the rejection of Claims 1-8, 10-12, 14, 16-19, 21, 23-30, 32, 34-36, 38-44, 46, 48, 52 and 54-60 is maintained.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

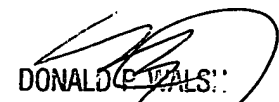
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey A. Shapiro  
Examiner  
Art Unit 3653

November 13, 2004



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